

§ 806.30

and maintained for the required period of time.

[62 FR 27191, May 19, 1997, as amended at 63 FR 42233, Aug. 7, 1998; 78 FR 55821, Sept. 24, 2013]

§ 806.30 FDA access to records.

Each device manufacturer or importer required under this part to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by FDA and under section 704(e) of the act, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records and reports.

[63 FR 42233, Aug. 7, 1998]

§ 806.40 Public availability of reports.

(a) Any report submitted under this part is available for public disclosure in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter; and

(2) Any personnel, medical, or similar information, including the serial numbers of implanted devices, which would constitute a clearly unwarranted invasion of personal privacy under § 20.63 of this chapter or 5 U.S.C. 552(b)(6); provided, that except for the information under § 20.61 of this chapter or 5 U.S.C. 552(b)(4), FDA will disclose to a patient who requests a report all the information in the report concerning that patient.

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

Subpart A—General Provisions

Sec.

807.3 Definitions.

Subpart B—Procedures for Device Establishments

807.20 Who must register and submit a device list?

21 CFR Ch. I (4–1–15 Edition)

807.21 How to register establishments and list devices.

807.22 Times for establishment registration and device listing.

807.25 Information required for device establishment registration and device listing.

807.26 Additional listing information.

807.28 Updating device listing information.

807.34 Summary of requirements for owners or operators granted a waiver from submitting required information electronically.

807.35 Notification of registrant.

807.37 Public availability of establishment registration and device listing information.

807.39 Misbranding by reference to establishment registration or to registration number.

Subpart C—Procedures for Foreign Device Establishments

807.40 Establishment registration and device listing for foreign establishments importing or offering for import devices into the United States.

807.41 Identification of importers and persons who import or offer for import.

Subpart D—Exemptions

807.65 Exemptions for device establishments.

Subpart E—Premarket Notification Procedures

807.81 When a premarket notification submission is required.

807.85 Exemption from premarket notification.

807.87 Information required in a premarket notification submission.

807.90 Format of a premarket notification submission.

807.92 Content and format of a 510(k) summary.

807.93 Content and format of a 510(k) statement.

807.94 Format of class III certification.

807.95 Confidentiality of information.

807.97 Misbranding by reference to premarket notification.

807.100 FDA action on a premarket notification.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374, 381, 393; 42 U.S.C. 264, 271.

SOURCE: 42 FR 42526, Aug. 23, 1977, unless otherwise noted.